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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,869	09/11/2003	Rebecca E. Cahoon	BB1294USCNT	6089

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/659,869

Applicant(s)

CAHOON ET AL.

Examiner

Medina A. Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 16, drawn to an isolated polynucleotide encoding a polypeptide, a chimeric, and host cell, classified in class 536, subclass 23.6, for example.
- II. Claims 10, drawn to an isolated polypeptide, classified in class 530, subclass 370, for example.
- III. Claims 11-13, drawn to a method for selecting a nucleic acid, classified in class 435, subclass 69.1, for example.
- IV. Claims 14-15, drawn to a method for obtaining a nucleic acid by PCR/hybridization method, classified in class 435, subclass 6.

For each of the inventions I-IV above, restriction to one of the inventions SEQ ID NO: 1-62 is also required under 35 USC 121. Applicant is required to elect one nucleic acid for Groups I, III and IV. For the invention of Group II, Applicant is also required to elect one protein sequence. Therefore, election is required of one of inventions I-IV and one of inventions SEQ ID NO: 1-62.

The inventions SEQ ID NO: 1-62 are distinct, each from the other because of the following reasons:

Inventions SEQ ID NO: 1-62 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

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808.01). In the instant case, the different inventions comprise structurally different nucleic acid sequences encoding structurally distinct polypeptide sequences. Also, the different sequences have different level of effects. In addition, since each nucleic acid/polypeptide is disclosed in specific SEQ ID NO, the structural difference between the nucleic acid/protein sequences would not have obvious over each other.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds that are unrelated to one another, as are different proteins are structurally distinct chemical compounds that are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Each sequence requires an independent search of the sequence databases. Absent evidence to the contrary, each such nucleotide is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 (see MPEP 803.04 and 2434). This requirement is not to be construed as a requirement for an election of species, since each nucleotide and amino acid sequence is not a member of single genus of invention, but constitutes an independent and patentably distinct invention.

Inventions I-II are patentably distinct products. The protein of group II and polynucleotide of group I are patentably distinct inventions for the following reasons. Proteins, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and protein is dependent upon the information

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provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded protein. In the present claims, a polynucleotide of group I does not necessarily encode a protein of group II. For example, the polynucleotide of claim 1 (a) would not encode the polypeptide of claim 10 (a). In addition, while a protein of group II can be made by methods using some, but not all, of the polynucleotides that fall within the scope of group I, it can also be recovered from a natural source using biochemical means. For instance, the protein can be isolated using affinity chromatography. For these reasons, the inventions of groups I and II are patentably distinct.

Furthermore, searching the inventions of groups I and II together would impose a serious search burden. In the instant case, the search of the proteins and the polynucleotides are not coextensive. The inventions of Groups I and II have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to proteins which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the protein but spoke to the gene. Searching, therefore, is not coextensive. In addition, the protein claims include proteins of 50 amino acids and having 80% identity to the sequence identified. This search requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis

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of technical literature. The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed proteins as explained above, which is not likely to result in relevant art with respect to the protein of group II. As such, it would be burdensome to search the inventions of groups I and II together.

Invention III is patentably distinct from any of the other groups because it requires positive selection methods that are not required by any of the other groups. The method also requires a major portion of a non-Myb polynucleotide. For example, step (a) of claim 11 can contain only 30 contiguous bases of SEQ ID NO: 1 and 100 contiguous bases of a non-Myb-related polynucleotide. Therefore, the invention of Group III would require a separate search.

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polynucleotide of Group I can be prepared by a materially different process such as chemical synthesis.

Inventions II and III or IV are patentably distinct because the isolated polypeptide of Group II cannot be used in the method of Group III or IV. Different groups require separate searches.

Inventions III and IV are patentably distinct because the two methods are not disclosed to be usable together. The method of Group IV requires hybridization and

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PCR conditions which are not required by the method of Group III. Therefore, the search of Group III would not overlap the search of Group IV.

Because these inventions are distinct for the reasons set forth above and have acquired a separate status in the art as shown by their different classifications and their recognized divergent subject matter and because the literature search required for the groups is not coextensive, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Contact information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (571) 272-0797. The Examiner can normally be reached Monday -Thursday from 8:00AM to 5:30PM and every other Friday from 9:00AM to 5:00 PM . Before and after final responses should be directed to fax nos. (703) 872-9306 and (703) 872-9307, respectively.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Amy Nelson, can be reached at (571) 272-0804.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

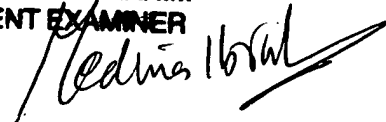
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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

8/6/05

Mai

MEDINA A. IBRAHIM
PATENT EXAMINER

A handwritten signature in black ink, appearing to read "Medina Ibrahim", written over the printed name and title.